

shall also inform him if the records sought are not available because they were compiled in reasonable anticipation of court litigation or formal administrative proceedings or are otherwise not available under § 21.41(b). Where appropriate, the letter shall also indicate whether the records are available under part 20 of this chapter (the public information regulations), and it may disclose the records in accordance with part 20.

(4) If the named Privacy Act Record System contains records about the individual that are retrieved by his name or other personal identifier, but a final determination has not yet been made with respect to disclosure of all of the records covered by the request, e.g., because it is necessary to consult another person or agency having an interest in the confidentiality of the records, the letter shall explain the circumstances and indicate when a final answer will be given.

(b) Except as provided in § 21.32, access to a record may only be denied by the Associate Commissioner for Public Affairs or his or her designate. If access to any record is denied wholly or in substantial part, the letter shall state the right of the individual to appeal to the Commissioner of Food and Drugs.

(c) If a request for a copy of the records will result in a fee of more than \$25, the letter shall specify or estimate the fee involved. Where the individual has requested a copy of any records about him and copying the records would result in a fee of over \$50, the Food and Drug Administration shall require advance deposit as well as payment of any amount not yet received as a result of any previous request by the individual for a record about himself, under this subpart or part 20 of this chapter (the public information regulations) before the records are made available. If the fee is less than \$50, prepayment shall not be required unless payment has not yet been received for records disclosed as a result of a previous request by the individual for a record about himself under this subpart or part 20 of this chapter.

[42 FR 15626, Mar. 22, 1977, as amended at 46 FR 8458, Jan. 27, 1981]

#### § 21.43 Access to requested records.

(a) Access may be granted to requested records by:

(1) Mailing a copy of the records to the requesting individual, or

(2) Permitting the requesting individual to review the records in person between 9 a.m. and 4 p.m. at the office of the FDA Privacy Act Coordinator, at the Freedom of Information Staff public room at the address shown in § 20.30 of this chapter, or at any Food and Drug Administration field office, listed in part 5, subpart M of this chapter, or at another location or time upon which the Food and Drug Administration and the individual agree. Arrangement for such review can be made by consultation between the FDA Privacy Act Coordinator and the individual. An individual seeking to review records in person shall generally be permitted access to the file copy, except that where the records include nondisclosable information, a copy shall be made of that portion of the records, with the nondisclosable information blocked out. Where the individual is not given a copy of the record to retain, no charge shall be made for the cost of copying a record to make it available to an individual who reviews a record in person under this paragraph.

(b) An individual may request that a record be disclosed to or discussed in the presence of another individual, such as an attorney. The individual may be required to furnish a written statement authorizing the disclosure or discussion in such other individual's presence.

(c) The Food and Drug Administration will make every reasonable effort to assure that records made available under this section can be understood by the individual, such as by providing an oral or written explanation of the records.

[42 FR 15626, Mar. 22, 1977, as amended at 46 FR 8458, Jan. 27, 1981; 69 FR 17290, Apr. 2, 2004]

#### § 21.44 Verification of identity.

(a) An individual seeking access to records in a Privacy Act Record System may be required to comply with reasonable requirements to enable the